REMARKS

The Office requested information regarding the manufacturer's instructions for the Delvotest® referred to on page 9 of the specification and information regarding when the Delvotest® was publicly available. Enclosed herewith is a copy of the product sheet for Delvotest® SP (Exhibit A), as well as a technical bulletin with photo instructions. In addition, it is believed that the Delvotest® has been on the market since 1974.

In addition, the Office has requested the names of products or services that have incorporated the claimed subject matter. Thus, also enclosed is a product sheet for the commercial product for testing anti-microbial residues in eggs (Exhibit B), which describes the protocol for use.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 246152016800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 5, 2005

Respectfully submitted,

By _____

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Product sheet

Delvotest® SP

Standard diffusion test for the detection of antibacterial substances in milk

Description

Delvotest® SP is a test system to test milk for the presence of antibacterial substances such as antibiotics and sulphonamides. It has been developed for a variety of applications ranging from a single test for testing the milk of an individual cow at the farmhouse to large-scale routine analysis in milk quality payment and milk control laboratories.
The test consists of a small test device with agar and a nutrient tablet. The test device consisting of single test ampoules or wells combined into multi test plates with 96 wells (6 blocks of 16 wells) containing a solid and buffered agar medium, a standardised number of spores of the test organism *Bacillus stearothermophilus var. calidolactis,* an antifolate trimethoprim and a purple coloured pH indicator (BCP).
The test kits contain all the necessary items (except incubating device) for execution of the test within the specific application and a product insert with instructions for use in different languages.
The principle of the test is based on diffusion of possible inhibitory substances, that may be present in the milk sample, into the agar thereby reducing growth and acid production by the test organism and delaying or preventing a colour change from purple to yellow of the agar.

Properties

The Delvotest® SP features a reliable and accurate antibiotic residues screening system which is recognised as an international standard. In many countries around the world this test serves as the arbiter for the determination of the absence or presence of inhibitory substances in milk, either for the industrial and/or at governmental level. The test is being used throughout the whole milk processing chain thereby facilitating standardisation and trade of milk and dairy products and minimising interpretation problems with regard to differences between detection levels of each of the antibiotics.
The tests are of consistent quality, having limited batch to batch variation, and minimum variations within one batch. The test is sensitive to a broad spectrum of antibiotic residues for instance, beta-lactams, sulphonamides, tetracyclines, aminoglycosides and macrolides.
The use of the test can therefor be integrated in existing milk quality control and milk quality payment schemes.

Delvotest® SP is FDA approved (appendix N testing) and AOAC performance tested under license #930704. Delvotest® SP is simple to perform and has an adequate shelf life.
The test may be used to control all types of milk and milk products as long as appropriate controls are applied.

Technical Service

Delvotest® SP from DSM is supported by an experienced Technical Service Team assuring the proper application of the product. This also provides access to additional scientific knowledge and international regulatory and application experience, collected both on the products from the DSM range as well as on other test systems in use by the dairy industry. Services further include staff training, participation in co-development work or application studies and trouble shooting.

Quality Assurance

DSM applies advanced quality management systems and the test production has been organised in line with the guidelines of ISO: 9001. Delvotest® SP is manufactured to meet the highest quality standards and can be provided with a certificate of analysis, a specification sheet and Technical Bulletins which include information on sensitivity and an indication of the spectrum of the test.

Distribution and Storage

Packaging of the products from the DSM range of antibiotic residue tests is of high quality in order to sustain international transport. Delvotest® SP test kits should be stored upright, in the dark and at a constant temperature below 15°C (preferably between 6-15°C). Protect from freezing.
Test kits are coded providing information on the lot (six digits)/and test type (two digits).
The "best-before-date" is indicated on the package.

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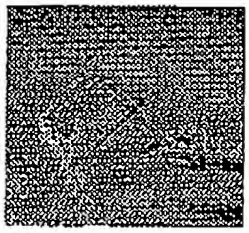
or our local representative :

Technical bulletin

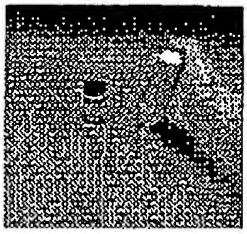
Delvotest®

Delvotest® multitest plate photo instructions

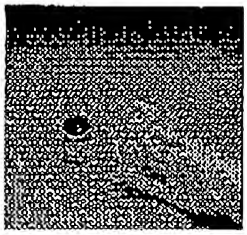


1. Determine the number of plates and/or blocks of 16 wells needed and cut them off with a sharp knife or scissors. Be careful not to damage the foil of remaining blocks.

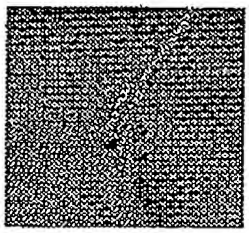
2. Remove the aluminium foil completely.



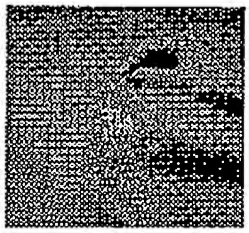
3. Use tweezers or a dispens to put one tablet into each well.



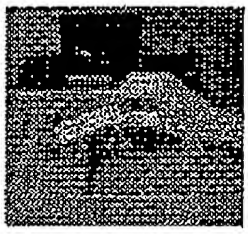
4. Check that each well has one tablet on the solid agar.



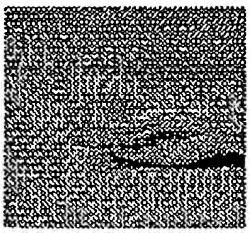
5. Pipette the negative control and the sample to be tested into the wells. Identify the position of each sample by the letters and figures on the multiplates.



6. Seal the blocks with the adhesive strips or sheets supplied with the test kit.



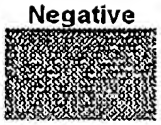
7.Incubate the blocks in a water bath (or plate incubator) preheated to 64°C. Check for time of negative control to turn to yellow.



8. Withdraw the blocks from the water bath after the negative control has turned yellow and read the results from the bottom of the blocks.

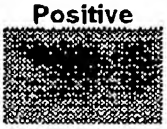
Delvotest® reading colours

Negative



Detection limit

Positive



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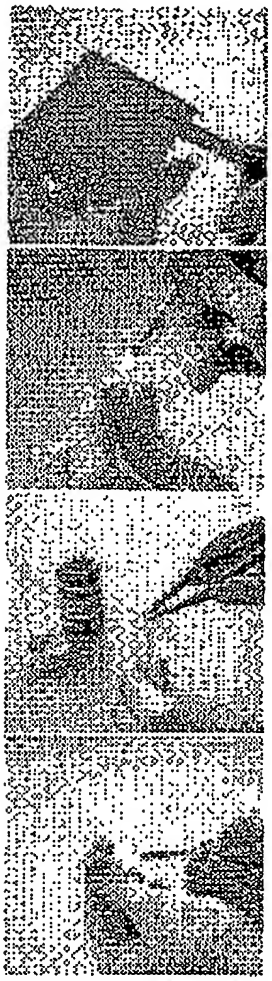
or our local representative :

Tbdtestplatephoto9912e2

Technical Bulletin

Delvotest®

Delvotest® ampoules photo instructions



1. Cut off the required number of ampoules with a pair of scissors. Be careful not to damage the foil of remaining ampoules.

2. Open ampoules by punching a hole in the aluminium foil with the syringe. Mark the ampoules for sample identification.

3. Add one nutrient tablet to each ampoule upon the solid agar with the tweezers. Do not touch the tables with your fingers.

4. Attach a new disposable pipette to the syringe. Do not touch the tip-end, which will be in contact with the milk.

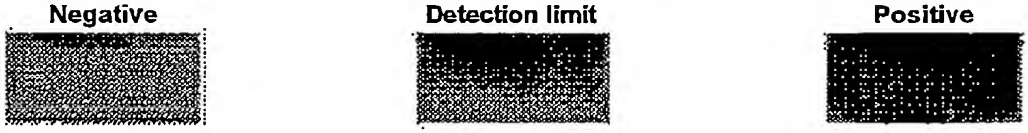
5. Depress the plunger completely, dip the tip in the milk sample and allow the plunger to return slowly under pressure of the spring.

6. Empty the syringe into the corresponding marked ampoule by slowly depressing the plunger of the syringe. Use a fresh disposable pipette for each milk sample.

7. Check, the temperature of the incubator (64°C ± 0.5°C). Put the ampoules into the incubator. Record the time and set timer for: P ampoules 2,5 hours or for SP ampoules 3 hours or use control time.

8. Read the colour of the lower 2/3 part of the solid agar in the ampoules after the required incubation time.

Delvotest® reading colours



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DSM

a DSM Product

Premi®Test sample procedure for eggs

Background

Using egg fluids in a microbial inhibition test may result in false positive results due to the presence of several naturally occurring inhibitors in egg yolk.
To prevent these inhibitors interfering with the test result a special protocol is required to use the Premi®Test for the detection of antibiotic residues in eggs.
Therefore DSM has developed a proprietary technology. This patented technology is described in this technical bulletin.
The influence of naturally occurring inhibitors can easily be prevented by inactivating the proteinaceous factors in eggs through a short heat pre-treatment step of the egg fluid.

Sample preparation method

- Wash hands before use and make sure to use a clean working surface.
- Make a hole of approximately 1-2 cm in the egg.
- Prick into the egg yolk, so the yolk will flow out of the egg easier with the egg white.
- Place the egg with the hole down on a clean bottle.
- After the egg is empty, close the bottle.
- Homogenize the egg fluid by shaking the bottle for several seconds.

Instructions for using Premi®Test

- Remove the aluminum foil carefully from the ampoule(s).
- Use a clean tip on the syringe.
- Transfer 100 µl of homogenized egg fluid to the agar in the ampoule, by pressing the syringe once and releasing it. It will automatically take up the required volume.
- Close the ampoules with the plastic foil supplied with the kit.
- Place the ampoule(s) in a water bath at 80°C for 10 minutes.
- After this heat pre-treatment, incubate the test in the DSM heating block incubator or in a water bath at 64°C (± 0,5 °C). Hereafter follow the procedure indicated in the manual of the Premi®Test.
- Incubate the sample for approx. three hours and check the color.
- Use a negative sample as control.

Reading the test results

- When the negative control changes color from purple to yellow (approx. 3 hours), the results can be read.
- Read the results from the bottom 2/3 part of the ampoule.
- A clear color change purple to yellow indicates that the antimicrobial compounds are below the Premi®Test detection limits.
- A purple color indicates the presence of antibiotics at or above the detection limits of the Premi®Test.

Version: Ttb ptest samp egg 0301
Date of issue: July 12, 2005

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